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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,424	08/04/2006	Steve B. Harris		8336

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JAY P. HENDRICKSON
1010 B STREET
SUITE 319
SAN RAFAEL, CA 94901

EXAMINER

HOLLOMAN, NANNETTE

ART UNIT	PAPER NUMBER
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1612

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,424	Applicant(s) HARRIS ET AL.	
	Examiner NANNETTE HOLLOMAN	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-86 and 89-109 is/are pending in the application.
- 4a) Of the above claim(s) 80-83 and 94-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-79 and 84-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/3/2010 and 8/19/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed December 22, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

The information disclosure statement filed September 3, 2010 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the WO 1999/39696 was previously submitted on the IDS filed August 19, 2010. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-76, 78 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Hong et al. (KR 1020010055736, disclosed by Applicant).

Hong et al. disclose a micro emulsion injection composition of propofol obtained by using 0.1 wt.% to about 10.0 wt.% propofol; 0.1 wt.% to about 20 wt.% polyethylene glycol 660 12-hydroxy stearate, which is a non-ionic surfactant, and a co-solvent (Abstract and reference claims 1-3); wherein the composition meets the limitation of not containing any other surfactant other than said nonionic surfactant. Hong et al. disclose in the Examples that the non-ionic surfactant and solvent are dissolved in propofol, which is being understood to meet the limitation of a “base composition”. Hong et al. disclose microemulsions are transparent, thermodynamically stable, are formed spontaneously and are good in homogeneity of particles (instant claims 78 and 79) (p. 4, lines 6-16). Furthermore, 0.1% propofol to 20% non-ionic surfactant would meet the limitation of more than 8 parts non-ionic surfactant to 1 part propofol. Therefore, the reference anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 74-76, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong et al. (KR 1020010055736, disclosed by Applicant).

It is believed Hong et al. anticipates the instant claims, but in the event that the composition of Hong et al. does not explicitly disclose “eight parts or more of the nonionic surfactant to one part of propofol” (that assumption is made here for the purposes of this ground of rejection only, purely *arguendo*), the following rejection is made. For the purpose of this rejection only, therefore, it will be assumed that Hong et al. differs from the instant claims insofar as it does not disclose the specific composition ratio of about eight parts or more of the nonionic surfactant to one part of propofol.

Hong et al. disclose a micro emulsion injection composition of propofol obtained by using 0.1 wt.% to about 10.0 wt.% propofol; 0.1 wt.% to about 20 wt.% polyethylene glycol 660 12-hydroxy stearate, which is a non-ionic surfactant, and a co-solvent (Abstract and reference claims 1-3); wherein the composition meets the limitation of not containing any other surfactant other than said nonionic surfactant. Hong et al. disclose in the Examples that the non-ionic surfactant and solvent are dissolved in propofol, which is being understood to meet the limitation of a “base composition”. Hong et al. disclose microemulsions are transparent, thermodynamically stable, are formed spontaneously and are good in homogeneity of particles (instant claims 78 and 79) (p. 4, lines 6-16).

It would have been obvious to one of ordinary skill in the art to have formulated the composition of Hong et al. with eight parts or more of the nonionic surfactant to one part of propofol, since the reference suggest using said ratio; specifically if 0.1 wt. %

propofol and 20 wt. % non-ionic surfactant is used. Therefore, said composition comprising said amounts of propofol and non-ionic surfactant would meet the limitation of about eight parts or more of nonionic surfactant to one part of propofol.

2) Claims 74, 77, 84-86 and 89-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong et al. (KR 1020010055736, disclosed by Applicant) as applied to claims 74-76, 78 and 79 above, and further in view of Pace et al. (US Patent NO. 6,726,919, previously disclosed).

Hong et al. is discussed above and further disclose the microemulsion may comprise 1 wt.% to about 50 wt.% of ethanol (reference claims 4 and 5). Hong et al. differs from the instant claims insofar as it does not disclose a composition comprising the specifically claimed water-immiscible solvent, ethyl oleate.

Pace et al. disclose micromatrices or microdroplets of a dispersion comprising propofol with a diluent, which meets the limitation of water-immiscible solvent, that can dissolve the propofol at all temperatures, i.e. ethyl oleate and alpha-tocopherol present in the composition at about 1% to about 8% (column 12, lines 45 and 46 and column 13, lines 9-10 and 35-36-column 14, lines 10-11, 22 and 55-57); wherein the compositions are stable as microemulsions in the presence of an antimicrobial agent for at least six months. Pace et al. also disclose the composition further comprises a non-ionic surfactant, i.e. polyoxy-ethylene sorbitan esters which meets the limitation of the structure of instant claims 74 and 80 (column 15, lines 49-52 and 59-60).

Pace et al. differ from the instant claims insofar as it does not disclose a self-microemulsifiable anhydrous composition.

It would have been obvious to one of ordinary skill in the art to have used diluents, i.e. ethyl oleate and alpha-tocopherol in the formulation of Hong et al. motivated by the desire to use diluents that can dissolve propofol at all temperatures as disclosed by Pace et al.

It would have been obvious to one of ordinary skill in the art to have formulated the composition of Hong et al. with not less than about three parts of the nonionic surfactant to one part of propofol, since the reference suggest using said ratio; specifically if 0.1 wt. % propofol and 20 wt. % non-ionic surfactant is used. Therefore, said composition comprising said amounts of propofol and non-ionic surfactant would meet the limitation of not less than about three parts of nonionic surfactant to one part of propofol.

The prior art discloses the use of 0.1 wt.% to about 10.0 wt.% propofol, 1 wt.% to about 50 wt.% of ethanol and about 1% to about 8% water-immiscible solvent. Thus, the prior art differs from the instant claims insofar as it does not disclose the particular endpoints recited therein, i.e. 3-5 parts water-immiscible solvent and 5-6 parts ethanol to about 10 parts propofol. It is well-settled, however, that even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Accordingly, it since an overlap plainly exists here, it would have been obvious to have selected values within the overlap, consistent with the reasoning of the

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Peterson decision.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571)270-5231. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612